GILEAD
Creating Possible

# RESONATE RFP Program

## Research to Advance HIV Treatment Outcomes

Gilead supports the research efforts of academic institutions, clinical investigators, and research networks that focus on improving outcomes across the treatment care cascade for people with HIV. Gilead evaluates proposals based on the need addressed by the proposed scientific question, validity of study methodology, timing of when results will fill a data gap of interest, and lack of redundancy with previous studies/data conclusions already available. Letters of intent (LOIs) will be used to determine who will be invited to submit a full application.

Bictegravir/emtricitabine/tenofovir alafenamide (B/F/TAF*) is a complete regimen for the treatment of HIV-1 infection in adults and pediatric patients weighing at least 14 kg, who have no antiretroviral treatment history or to replace the current antiretroviral regimen in those who are virologically suppressed on a stable antiretroviral regimen with no known or suspected substitutions associated with resistance to bictegravir or tenofovir.[1]

Lenacapavir (LEN) is a novel first-in-class capsid inhibitor, which in combination with other antiretroviral(s), is indicated for the treatment of HIV-1 in heavily treatment-experienced adults with multidrug resistant HIV-1 infection failing their current antiretroviral regimen due to resistance, intolerance, or safety considerations.[2]

Gilead is making a specific request for research study proposals in the disease area of HIV treatment, as further scientific data are needed on B/F/TAF and LEN to support medical management and decisions of clinicians and people with HIV. Through the RESONATE RFP Program, Gilead will evaluate and potentially support research proposals which address one or more of the following research topics:

1. Patient Reported Outcome (PRO) (e.g. treatment satisfaction, quality of life assessments) and effectiveness data on B/F/TAF in prioritized populations* of people with HIV.

   *Prioritized populations include the following: women across all stages of development, elderly (can be defined as individuals over 50, over 65, and over 70 years of age), people living with long term HIV, and people with chronic comorbidities. Populations of specific regional interest are: migrants in Australia, Canada, and Europe; immigrants of Latin American descent in the United States, perinatally infected children in South Africa, and chemsex users in Europe.

2. Effectiveness and safety outcomes of B/F/TAF among people with HIV with historical resistance (such as resistance to older INSTIs)

3. Evaluate implementation outcomes (e.g. feasibility, acceptability) of new clinical tools, resources, practices and protocols that have led to successful LEN implementation for the treatment of HIV-1 in heavily treatment-experienced adults with multidrug resistant HIV-1

4. Research on the following areas of the HIV treatment care cascade:

    - Use of PRO tools to assess the effectiveness of patient care models to sustain engagement in HIV care, facilitate shared decision making for treatment optimization, and support evidence-based interventions for treatment optimization
    - Effectiveness of interventions, tools, programs to support immediate ART in both clinical and nonclinical settings
    - Adherence, patient satisfaction, quality of life, and safety outcomes among virally suppressed people with HIV on complex regimens
    - Outcomes (engagement in care, adherence, and patient satisfaction) among people who have a choice of different treatments compared to those who lack choices
    - Relinking to treatment people with HIV who have fallen out of care in regions outside of the US

Please discuss other research topics not listed above with your local Gilead Medical Scientist.

**Application Criteria**

- Investigators with proposals that meet the criteria for a standard Gilead ISR are encouraged to apply.
- Both investigator-sponsored research study proposals and collaborative research study proposals (developed in conjunction with Gilead) will be considered.
- To enhance scientific robustness, we encourage applicants to submit LEN study proposals that capture and describe outcomes beyond single patient cases (for example, through study proposals involving additional study sites/institutions).
- Proposals will only be reviewed from countries where B/F/TAF or LEN have regulatory approval and are commercially available. Questions about availability of B/F/TAF or LEN in specific regions can be directed to RESONATE@gilead.com
- Proposals that request study drug support in addition to funding will be considered.
- We recommend that submitted proposals:
    - Can be completed within 18 months after contract execution
    - Have a well-defined research question with supporting sound scientific hypothesis, objectives and endpoints.
    - Collect appropriate metrics using defined and specific data collection methods
    - Have a plan to present results in scientific forums and to other organizations, and to publish results in a peer reviewed journal
    - Note potential scalability and sustainability of the program once funding is complete (when applicable)
    - Highlight generalizability to other practice settings

- **As the study sponsor, the principal investigator will be responsible for compliance with all laws and regulations applicable to research sponsors, including satisfying local requirements and obtaining all necessary regulatory approvals prior to beginning the study.**

**Awards shall be for research purposes only. Requests that include routine medical care or other costs associated with routine medical care will not be considered.**

## Submission Deadlines and Application Process

### Letter of Intent (LOI) Submission Window

To be considered for funding under the RESONATE RFP Program, applicants must submit a LOI that is no longer than two pages, contains a concise overview of the proposed project and includes the total estimated budget.

**Gilead will evaluate and rank LOIs received on a monthly basis until funds are exhausted. It is strongly recommended to submit earlier rather than later so that proposals can be evaluated while funding is still available.**

- **July 7, 2025**: Submission window opens
- **August 4, September 1, October 6, November 3 (23:59 PST)**: Submission deadlines for LOI review
- **November 3, 2025 (23:59 PST)**: Submission window closes

LOIs must be submitted via the Gilead Optics online portal in the RESONATE LOI section in order to be considered for this program.

LOIs are not binding documents on either party. The purpose of the LOI is to provide a brief summary of the proposed study to enable Gilead to determine on a preliminary basis whether the proposed study and related budget are aligned with the criteria, timeline and scope of this RFP.

Questions about the RFP or the application process can be submitted to your local Gilead Medical Scientist or RESONATE@Gilead.com .

A review of the LOIs will result in invitations for selected LOI applicants to submit a full application with detailed budget. Below are the timelines for full submissions.

- **By November 30, 2025**: Notice of LOI outcome, with invitations for full application submission
- **By December 30, 2025 (23:59 PST)**: Deadline for receipt of full application
- **By February 15, 2026**: Notice of full application outcome

Applications must be completed in Gilead Optics following invitations to submit full proposals.

**Budget Considerations**
Gilead plans to award up to $4,000,000 in funds for these research proposals, dependent upon availability of funds and receipt of meritorious applications. Gilead anticipates that up to 10 awards will be granted. Any proposal greater than $400,000 should be discussed with your Gilead Medical Scientist prior to submission. Proposed overhead costs should not exceed 30% of total budget.

Gilead's approval of awards will depend on the availability of funds and receipt of meritorious and complete proposals. Awards shall be granted solely on the merit of the research and alignment with the criteria of this program.

**Review Process**
LOIs will be rigorously reviewed by an internal Gilead committee. Each LOI that meets program requirements and is complete, will be assigned to multiple reviewers. Each reviewer will evaluate and rank how well the proposal addresses one or more of the research topics, the potential impact of the study, the strength of the objectives/study design and sustainability/scalability of the methods under study. Applicants with the top LOI submissions will be offered the opportunity to submit a full proposal, which will be similarly reviewed.

**No Guarantee of Funding**
Gilead reserves the right to approve or decline any application at its sole discretion. Submission of an LOI or a full application does not guarantee funding.

**No Inducement or Reward**
Gilead approval of awards does not take into account the past, present, or future volume or value of any business or referrals between the parties. Awards are not being given, directly or indirectly, as an inducement or reward with respect to the past or potential future purchase, utilization, recommendation or formulary placement of any Gilead product. Furthermore, except for the use of the Gilead product in an approved award/ research, the awardee is not required to purchase, order, recommend or prescribe to any patients any products manufactured by or available through Gilead.

**About Gilead Sciences**
Gilead Sciences, Inc. is a biopharmaceutical company that discovers, develops and commercializes innovative therapeutics in areas of unmet medical need. The company's mission is to advance the care of patients suffering from life-threatening diseases worldwide. Gilead has operations in more than 30 countries worldwide, with headquarters in Foster City, California

**B/F/TAF refers to Gilead's Biktarvy® (either bictegravir 50 mg / emtricitabine 200 mg / tenofovir alafenamide 25 mg tablets for adult and pediatric patients weighing ≥25kg or bictegravir 30 mg / emtricitabine 120 mg / tenofovir alafenamide 15 mg tablets for pediatric patients weighing ≥14 kg to <25 kg).*
*The use of B/F/TAF in patients with a history of treatment failure is investigational and the safety and efficacy of this use has not been determined. Please always refer to your local/regional label for B/F/TAF.*

**References**


1. Biktarvy USPI, Gilead Sciences, October 2024. Available at: https://www.gilead.com/~/media/files/pdfs/medicines/hiv/biktarvy/biktarvy_pi.pdf
2. Sunlenca USPI, Gilead Sciences, November 2024. Available at: https://www.gilead.com/-/media/files/pdfs/medicines/hiv/sunlenca/sunlenca_pi.pdf